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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,550	06/29/2006	Masayuki Tanaka	Q90646	3838

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
RAGHU, GANAPATHIRAM	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,550	TANAKA ET AL.	
	Examiner	Art Unit	
	GANAPATHIRAMA RAGHU	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Claims 1-27 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 1-8, 16 and 17, drawn to a catalyst capable of cleaving specifically one sugar chain or two or more sugar chains selected from the group consisting hyaluronic acid, chondroitin sulfate A, chondroitin sulfate C and chondroitin sulfate D, wherein said catalyst is a polypeptide of SEQ ID NO: 2 or wherein said polypeptide comprises an amino acid sequence having deletion, substitution, insertion or transposition of one or several amino acids in the amino acid sequence of SEQ ID NO: 2 and fusion proteins comprising said polypeptide.

Group II: Claims 9-12, 22 and 23, drawn to method of cleaving specifically one sugar chain or two or more sugar chains and to a method of specifically producing sugar chains having a decreased molecular weight, which comprises one sugar chain or two or more sugar chains selected from the group consisting hyaluronic acid, chondroitin sulfate A, chondroitin sulfate C and chondroitin sulfate D, wherein said method comprises reacting said sugar chains with a polypeptide of SEQ ID NO: 2 or wherein said polypeptide comprises an amino acid sequence

having deletion, substitution, insertion or transposition of one or several amino acids in the amino acid sequence of SEQ ID NO: 2.

Group III: Claim 13-15, drawn to method for producing a catalyst or medicament, wherein said method comprises expressing a protein by a DNA that encodes a polypeptide of SEQ ID NO: 2 or wherein said polypeptide comprises an amino acid sequence having deletion, substitution, insertion or transposition of one or several amino acids in the amino acid sequence of SEQ ID NO: 2 and has activity specifically producing sugar chains having a decreased molecular weight, which comprises one sugar chain or two or more sugar chains selected from the group consisting hyaluronic acid, chondroitin sulfate A, chondroitin sulfate C and chondroitin sulfate D.

Group IV: Claims 18-21, drawn to method for treating a disease in which one sugar chain or two or more sugar chains selected from the group consisting hyaluronic acid, chondroitin sulfate A, chondroitin sulfate C and chondroitin sulfate D is excessively present in the body tissue by administering the polypeptide of group I.

Group V: Claims 24-27, drawn to use a protein for the manufacture of a medicament, said protein capable of cleaving specifically one sugar chain or two or more sugar chains selected from the group consisting hyaluronic acid, chondroitin sulfate A, chondroitin sulfate C and chondroitin sulfate D, wherein said catalyst is a polypeptide of SEQ ID NO: 2 or wherein said polypeptide comprises an amino acid sequence having deletion, substitution, insertion or

transposition of one or several amino acids in the amino acid sequence of SEQ ID NO: 2 and fusion proteins comprising said polypeptide.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following categories:

1) A product and a process specially adapted for the manufacture of said product or

2) A product and process of use of said product; or

3) A product, a process specially adapted for the manufacture of said product and a use of said product; or

4) A process and an apparatus or means specifically adapted for carrying out the said process; or

5) A product, a process specially adapted for the manufacture of said product and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states: If an application contains more or less than one of the combination of categories of in an invention set forth in paragraph (b) of this section, unity of invention might not be present.

In addition, the PCT does not provide for multiple products or methods within single application, therefore, unity of invention is lacking with regard to Groups I-V; see 37 CFR 1.475. 37 CFR 1.475 (d) also states: If multiple products, processes of manufacture or uses are claimed,

the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) 1.47(c).

37 CFR 1.475(e) further states; the determination whether a group of invention is so linked as to form a single inventive concept shall be without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The polypeptides of Groups I-V do not share a corresponding special technical feature, because the prior art clearly teaches isolation and purification of a protein having hyaluronidase activity that is capable of cleaving hyaluronic acid and the use of said polypeptide as a medicament for various disease conditions (see Stern et al., WO 99/298841, cited in IDS). Therefore, the only shared technical feature of these claims polypeptides having hyaluronidase activity and capable of cleaving specifically one sugar chain or two or more sugar chains selected from the group consisting hyaluronic acid, chondroitin sulfate A, chondroitin sulfate C and chondroitin sulfate D , the method of making polypeptides and use of said polypeptides in Groups I-V, does not constitute a special technical feature as defined in PCT Rule 13.2 as it is not a feature which defines a contribution of the claimed invention makes over the prior art. Furthermore, the methods of Groups II-V do not share any technical feature as they comprise unrelated steps and produce unrelated effects and 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election

This application contains claim directed to the following patentably distinct species of the claimed invention:

Claims 1-27 (Groups I-V) drawn a catalyst/protein capable of cleaving specifically one sugar chain or two or more sugar chains selected from the group consisting of:

a) hyaluronic acid,

b) chondroitin sulfate A,

c) chondroitin sulfate C and

d) chondroitin sulfate D

Applicant is required, in reply to this action, to elect a single species or a particular, defined combination of two or more of these species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (a single group from a) to d) or a specific defined combination of two or more of these species of a)-d)) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims **1-27** are generic.

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
Mar. 07, 2008.

/Rebecca E. Prouty/
Primary Examiner,
Art Unit 1652